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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,708	10/03/2003	Charlotte A. Kensil	8449-322-999	9606

20583 7590 04/06/2007

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
KIM, YUNSOO	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/679,708	KENSIL ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-52,54,58,59 and 61-70* is/are pending in the application.

4a) Of the above claim(s) *54,61 and 62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-52,58,59 and 63-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/12/07,2/15/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/12/07 has been entered.

2. Claims 46-52, 54, 58, 59 and 61-70 are pending.

Claims 54, 61 and 62 stand withdrawn from further consideration by the examiner 37 CFR 1.142(b) as being drawn to a nonelected species.

Claims 46-52, 58, 59 and 63-70 drawn to a method for enhancing immune response with a composition comprising an antigen, wherein the antigen is a protein, saponin adjuvant, and an excipient, wherein the excipient is a beta-cyclodextrin are under consideration in the instant application.

3. Applicant's submission of IDS filed on 1/12/07 and 2/15/07 has been considered. However, IDS filed on 1/12/07 has been crossed out as being a duplicate of the IDS filed on 2/15/07. Moreover, IDS references, B06, B08 and B11 have been considered to the extent to the abstract as being foreign documents. Applicant is invited to provide a translation if the entire document is required to be considered.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 46, 49-52, 58, 59 and 63-70 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6,146,632 (of record) as is evidenced in the specification of the instant application on p. 2-3 in view of U.S. Pat. No. 4,727,064 (of record) for the reasons set forth in the office action mailed on 11/7/06.

Applicants' arguments filed on 1/12/07 have been fully considered but they were not persuasive.

Applicants argue that there is no motivation to combine the references and the applicants' provision of the unexpected results of improved tolerance to the pain in association of QS-21 saponin and cyclodextrin has not been addressed. Applicants further argue that the hydroxypropyl-gamma-dextrin (HPCD) is only suitable with the drugs with the low water solubility that tend to crystallize.

The Examples 1 and 6 where Applicants contend to show the unexpected results of improved tolerance to the pain associated with QS-21 saponin and cyclodextrin are not commensurate with the scope of the invention. The invention is drawn to a method for enhancing an immune response to an antigen with a composition comprising adjuvant and excipient, not to improve tolerance associated with the pain from administration of QS-21 saponin in the presence of cyclodextrin. Moreover, as discussed in the office action mailed 11/07/06, the cyclodextrin is known to reduce tendency to cause irritation (the '064 patent, col. 1-2, in particular).

Contrary to Applicants' assertion that the HPCD is only suitable with the drugs with the low water solubility that tend to crystallize, HPCD is suggested to be composed with various other drugs including steroid. Saponins are glycosides of steroids, steroid alkaloids or triterpenes found in plants.

As taught in the '064 patent, the hydroxypropyl-beta-cyclodextrin (HPCD) improves solubility which reduces tendency to cause irritation and stabilizes wide range of drugs including steroid, exhibits low toxicity and extends shelf life and widely used as an excipient (e.g. additive) (col. 1, lines 25-45, col. 2, lines 36- 60, and claims 1-28, in particular).

Therefore, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to employ the HPCD as an excipient taught by the '064 patent in an immunogenic composition comprising an QS-21 and antigen as taught by the '632 patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the '064 patent teaches the HPCD adds stability to any drugs and extends shelf life, reduces irritation and exhibits low toxicity (col. 1, lines 25-45, col. 2, lines 36- 60, and claims 1-28, in particular).

From the teachings of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

6. Claims 46-52, 58, 59 and 63-70 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,057,540 (of record) as is evidenced in the specification of the instant application on p. 2-3, 7-10 in view of U.S. Pat. No. 4,727,064 (of record) for the reasons set forth in the office action mailed on 11/7/06.

Applicants' arguments filed on 1/12/07 have been fully considered but they were not persuasive.

Applicants argue that there is no motivation to combine the references and the applicants' provision of the unexpected results of improved tolerance to the pain in association of QS-21 saponin and cyclodextrin has not been addressed. Applicants further argue that the hydroxypropyl-gamma-dextrin (HPCD) is only suitable with the drugs with the low water solubility that tend to crystallize.

In light of the discussion provided above, in the section 5 of this action, the combination of the reference teachings remains obvious.

7. No claims are allowable.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Yunsoo Kim
Patent Examiner
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March 22, 2007